K111997

APR - 6 2012

## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

**Applicant:** KARL STORZ Endoscopy America, Inc.
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**Contact:** Winkie Wong
Associate Regulatory Affairs Specialist

**Date of Preparation:** July 11, 2011

**Device Identification**:

Common Name: Gastroscopes and Accessories, Flexible/Rigid

Trade Name: (optional) Image1 GI CCU

**Indications:** The Image1 GI CCU is to be used in conjunction with a light source and endoscope by physician/endoscopist to provide optical visualization via a video monitor for endoscopic observation and image recording during diagnostic and therapeutic procedures of the upper/lower digestive tract.

**Device Description:** The Image1 GI CCU consists of two components: the camera control unit and a keyboard. The Image1 GI CCU is used in conjunction of a videoscope and a light source, which transmit the video signals to camera control unit (image processor) to provide optical visualization via a video monitor.

**Substantial Equivalence:** The Image1 GI CCU is a modification of the already cleared Image1 Video Imaging System, previously known as KSI's New Camera Architecture (NCA) Video Imaging System (K003325). The underlying fundamental technology and intended use remains unchanged. All the changes were made to enhance image quality specifically for GI indication and to allow to print an image via the USB printer or store an image to a USB storage device for documentation purpose. Internal safety and performance testing are performed to ensure the safety and efficacy of the device.

The Image1 GI CCU is also substantially equivalent to Fujinon EPX-4400HD Video Processor and Light Source (K102466). Both devices consist of a video processor (CCU) and a keyboard. They also share the same indications for use and fundamental technologies, which offers external image storage capability and

similar features such as: Brightness Control, Enhancement Control, Light Source Control, White Balance, Zoom and HD Capability. The differences between the subject and predicate devices are the subject device incorporates the KARL STORZ Communication Bus (SCB) system for ease of use.

**Conclusion:** The Image1 GI CCU is substantially equivalent to the identified predicate devices and the differences between the subject and the predicate devices do not raise any new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Ms. Winkie Wong
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APR -6 2012

Re: K111997
Trade/Device Name: Image1 GI CCU
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET
Dated: March 13, 2012
Received: March 14, 2012

Dear Ms. Wong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**Indication for Use**

K 111997

**510(k) Number (if known):** ~~Not yet assigned~~

**Device Name:** Image1 GI CCU

**Indication for use:** The Image1 GI CCU is to be used in conjunction with a light source and endoscope by physician/endoscopist to provide optical visualization via a video monitor for endoscopic observation and image recording during diagnostic and therapeutic procedures of the upper/lower digestive tract.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111997